

BOARD OF PHARMACY

Final Statement of Reasons

Subject Matter of Proposed Regulations: Disciplinary Guidelines

Section Affected: 1760

Hearing Date: January 24, 2001

Updated Information

The changes made by the board were made by the board and were the subject of a 15 day notice are summarized as follows:

1. Removal of an irrelevant regulation from the list of sections whose violation was classified in Category 1.
2. Removal of the requirement that the board revoke probation for non-payment.
3. Addition of language permitting the board to extend probation so that a probationer can complete the work requirement imposed as a term of probation.
4. Addition of language prohibiting pharmacists who have been suspended from practice from functioning as a pharmacy technician.
5. Removal of the requirement that probationers must not be in the presence of individuals using illicit drugs.
6. Removal of the requirement that a probationer post a notice of probation at his/her place of work.

Comments Received During the 45-Day Comment Period (December 1, 2000 to January 15, 2001)

The board received two letters commenting on the proposed regulation.

1. In a letter dated December 13, 2000, Mr. Ronald Marks provided the board with comments on numerous provisions of the proposed guidelines.

Mr. Marks stated that failure to pay board costs should not result in automatic revocation of probation without benefit of a hearing.

The board responded that Mr. Marks' comment was appropriate and the language that required the revocation of probation for non-payment was removed from the guidelines.

Mr. Marks further stated that it should not constitute a violation of probation if a pharmacist is working below set minimum hours while on probation.

The board responded that Mr. Marks' comment was appropriate and language was added to the guidelines that provides flexibility on this question (see item 13 on page 24 of the modified guidelines).

Mr. Marks further stated that restriction of activities requiring professional judgement if a suspension from practice is in effect is too vague to be enforceable.

The board responded that “professional judgment” is not vague. What constitutes activity requiring the judgment of a pharmacist is defined in law. Those tasks that require a pharmacist license are defined throughout the Pharmacy Law (Business and Professions Code 4000 et seq.), most notably in Sections 4051 and 4052 of the Business and Professions Code and in Title 16, Section 1793.1. Some of those tasks have been determined to be non-discretionary and may be delegated to unlicensed staff under the supervision of a pharmacist. Title 16, Sections 1793.2 and 1793.3 of the California Code of Regulations specifies which tasks may be delegated to unlicensed personnel. Those tasks that may be delegated do not, by definition, require the judgment of a pharmacist. All other tasks that require a pharmacist license are those tasks that require professional judgment.

Mr. Marks further stated that use of mental health examinations by a single practitioner to determine safety for practice vests too much authority in one practitioner’s “educated guess.” Mr. Marks indicates that the board should require the concurrence of two other mental health professionals before determining that it is unsafe for a pharmacist to practice.

The board responded that mental health examinations are not “educated guessing.” Mental health examinations conducted by qualified mental health professionals are scientifically valid and are used in the enforcement programs of many professional licensing boards.

Mr. Marks further stated that automatic suspension of a license for termination from the pharmacist recovery program violates the right to due process.

The board responded that the language regarding automatic suspension when terminating from the Pharmacist Recovery Program does not violate due process rights. This language only applies to those participants who enter the program under stipulated settlement or by the order of the board after an administrative law judge has considered an accusation by the board through a hearing. In those cases, the settlement agreement or the board’s order provides for this automatic suspension. In the stipulated settlement, the pharmacist agrees to this condition freely. In orders from the board, participation in the program is given in lieu of stronger disciplinary action.

It should be noted that participants are only terminated from the program for severe non-compliance and those participants demonstrate an immediate threat to public safety. Furthermore, the pharmacist does not lose his/her due process rights under this provision. This only provides for the suspension of a license. At that point the board must begin the process of revoking a pharmacist’s license which requires an administrative hearing.

Mr. Marks further stated that ongoing drug and alcohol screening for the full period of probation is excessive and testing is not necessarily reliable.

The board responded that drug and alcohol screening is an optional condition of probation and not a standard condition of probation. It is only applied in cases where appropriate (generally cases of substance abuse by the pharmacist) and ongoing drug and alcohol screening is

commonly accepted as a vital part of any substance abuse treatment program and is necessary to assure the probationer's compliance with the probation order. The probation order establishes the period during which closer monitoring of a pharmacist is warranted, and while the board has discretion to determine when to require drug and alcohol screening, it is likely to decrease over the course of the probation term. The board uses the services of reliable agencies to perform the drug screening required.

Mr. Marks further stated that restriction from areas where drugs or alcohol is present is beyond the board's authority.

The board responded that the comment was appropriate and removed the language from the guidelines.

Mr. Marks further stated that posting a notice of probation for a premises whose license is on probation is punitive and exceeds requirements for compliance.

The board responded that the comment was appropriate and removed the language from the guidelines.

Mr. Marks stated that several of the codes that may be subject to violation are confusing and that the designations for some categories are not consistent with severity or risk to public health and safety. With regard to settlement offers going before the board, he stated that there should be published guidelines as to when this occurs.

The board responded that it exercises great care to assure the consistency and validity of its classification of offenses. If Mr. Marks wishes to identify specific code sections that are confusing or offenses that are categorized in a manner inconsistent with their severity, then the board would give serious consideration to those items. However, absent providing such specific information, it is difficult for the board to respond to such a vague comment.

The board further responded that any settlement offer made by the respondent will be considered by the board and therefore no guidelines are needed. Those offers can be communicated to the deputy attorney general handling the case at any time.

Lastly, Mr. Marks stated that he would like a meeting convened by the board or counsel for the board and those attorneys who frequently represent respondents in order to receive input on the procedures that involve imposition of discipline.

The board responded that such meetings are convened periodically, but there is no need to delay action on the guidelines to permit such a meeting. Mr. Marks or any other member of the public is free to make such inquiries or provide input to the board through a number of mechanisms. Those mechanisms include addressing the board during time provided at each board meeting for comment from the public, commenting at public meetings of the board's Enforcement Committee, or submitting written comment to the board at any time.

2. In a fax transmission received at the board office on January 12, 2001, comments were submitted jointly by the California Pharmacists Association, Longs Drug Stores, United Food and Commercial

Workers' Union Local 770 and the Guild of Professional Pharmacists (hereinafter the commenters). These entities stated their concerns regarding the board's current disciplinary process and the use of Disciplinary Guidelines.

The commenters stated that the board's strict adherence to its guidelines results in the imposition of harsh and punitive terms on those who are subject to disciplinary action.

The board responded that the Disciplinary Guidelines serve as a starting point for establishing the terms of discipline. However, the terms of discipline are established either through negotiation with the respondent's counsel in a settlement agreement or are imposed by the board after a hearing before an administrative law judge. The board and its counsel consider each case individually when negotiating the terms for a settlement. The guidelines exist to provide a measure of consistency in board disciplinary actions, but are only guidelines and permit the board to tailor the terms of discipline to the individual case. The terms of discipline are established to fulfill the board's principle mandate of public protection..

The commenters further stated that the pharmacist-in-charge is always implicated in board action regardless of the circumstances.

The board responded that it is commonplace for the pharmacist-in-charge (PIC) to be subject to disciplinary action for violations in the pharmacy because of the unique responsibilities of that position. Section 4113 of the Business and Professions Code requires the PIC to be responsible for the pharmacy's compliance with all state and federal laws relating to the practice of pharmacy. Therefore, when a pharmacy law violation occurs in that pharmacy, the PIC frequently bears some responsibility. The accountability of the PIC is important because there is no requirement that pharmacies be owned by pharmacists. As such it is the PIC who has a professional responsibility for the operation of a pharmacy.

The commenters further stated that the timing for filing of accusations is often well after the incident.

The board responded that this is not a subject addressed in the Disciplinary Guidelines. The timing of case filing is dependent on the filing of a complaint with the board, not necessarily with the occurrence of the event. The board investigates cases after complaints have been filed and then takes action based on whether the investigation substantiates the complaint. If the case warrants the filing of an accusation, then the investigation is forwarded to the Department of Justice which is responsible for drafting the accusation and representing the board in the administrative hearing process.

The commenters further stated that the discipline meted is not necessarily appropriate for the violation.

The board responded that this comment is vague and the commenters should identify the specific elements in the Disciplinary Guidelines that are inappropriate. Without identifying specific elements of the Disciplinary Guidelines that are problematic, it is difficult for the board to respond in a meaningful manner. Additionally, the board's discipline is linked to the elements of each specific case. However, the guidelines help assure that the resolution of comparable cases are not grossly dissimilar.

The commenters further stated that the disciplinary actions by the board appear to be harsher as time passes and akin to criminal sanctions.

The board responded that it is unaware of any information that indicates progressively harsher disciplinary terms in board cases. However, if the commenters have such data, the board would give it full consideration in evaluating its disciplinary actions. The board further responded that there is no aspect of its disciplinary proceedings that are akin to criminal sanctions. Respondents to accusations filed by the board are not subject to imprisonment or fines which characterize criminal sanctions.

The commenters further stated that the approach the board takes in considering evidence of rehabilitation in disciplinary action is not focused on valuing rehabilitation to the extent that they would prefer.

The board responded that Section 4313 of the Business and Professions Code requires the board to give precedence to public protection over rehabilitation. Furthermore, in situations where public protections and evidence of rehabilitation are in conflict the board is required to give priority to public protection.

The commenters further stated that the board is inconsistent in its application of disciplinary action and does not supply justification for its actions to the accused. They stated that the board should consistently take into account all the factors listed on page three of the Disciplinary Guidelines and treat licensees as individuals.

The board responded that these Disciplinary Guidelines are established to support the consistent application of the board's disciplinary authority.

The board further responded that the commenters were opposed to the board's "strict adherence" to the Disciplinary Guidelines in an earlier comment. This apparent inconsistency needs to be resolved before the board can fully respond to the commenters' concerns on this question.

The board further responded that it is unable to respond to the commenters' concern for treating case individually in light of their concurrent concern with the board's inconsistent application of disciplinary action.

The commenters further stated that a licensee is not able to present evidence of the factors that would support lesser action prior to an accusation being filed.

The board responded that it only pursues disciplinary action following the conclusion of an investigation of a complaint that substantiates a violation of law of sufficient severity to warrant the filing of an accusation. Permitting a preaccusation hearing would provide a disincentive for licensees to be fully forthcoming and cooperative during the investigation. The licensee has the ability to provide any and all evidence he/she feels is relevant during the course of that investigation. Furthermore, the licensee has the ability to present evidence supporting lesser discipline during the administrative hearing process and is free to argue that evidence before the administrative law judge.

The commenters further stated that pharmacists are unfairly sanctioned by the board.

The board responded that the commenters should indicate which specific provisions of the Disciplinary Guidelines are unfair so that the board may consider them.

The commenters further stated that the board favors the word of the consumer over that of the pharmacist and his or her general practice routine.

The board responded that it considers all the evidence gathered in an investigation including the testimony of both the licensee and the consumer. That evidence is considered by the administrative law judge during the hearing process and must conclude that there is clear and convincing evidence of a violation.

The commenters further stated that the terms used in the Disciplinary Guidelines are undefined which results in licensees not knowing what they mean.

The board responded that it has drafted the Disciplinary Guidelines in plain English. The terms used in the Disciplinary Guidelines have their common English meaning. However, if the commenters have specific terms whose usage is unclear to them, they should provide those terms to the board for further clarification.

The commenters further stated that the infrequent use of the terms “corrections and “field admonishments” indicates that the board is issuing inappropriate discipline in disproportionate quantity.

The board responded that the Disciplinary Guidelines are provided for consideration of professional discipline (the filing of an accusation for administrative hearing) not for other, less stringent and less formal, types of enforcement actions (field admonishment, notice of violation, citation and fine, and formal admonishment). The relative infrequency of those terms in the Disciplinary Guidelines is a consequence of the document’s subject matter, not an indicator of “inappropriate discipline in disproportionate quantity.”

The commenters further stated that the board should consider all factors in every circumstance.

The board responded that it does consider the evidence gathered in the investigation and page three of the Disciplinary Guidelines provides a list of 14 items to be considered when determining the penalties to be applied. That list is not exclusive and other factors may be considered as appropriate.

The commenters further stated that a committee comprised of three board members – two practitioners and one public member, should determine the level of discipline to be taken for each board action considered,

The board responded that having board members reviewing cases is problematic. Each board member who reviews cases in the manner suggested by the commenters would be excluded from considering the case should the board review the proposed determination from the administrative

hearing process. Board members would be forced to recuse themselves because they would be aware of information regarding the case not included in the decision considered by the other board members. Excluding three members from any decision seriously impairs the ability of the board to make determinations. Six votes are required to form a board majority, so with three members recused and either two absences or vacancies would require concurrence of all the remaining members to take action.

The commenters further stated that inspection and investigation reports should contain mitigating information provided by the licensee in question.

The board responded that licensees are free to provide any information they feel is relevant to board inspectors during the investigation. Relevant information gathered during the course of an investigation is included by the inspector in the investigation report.

The commenters further stated that the board's terms and conditions of probation should be dictated by the circumstances surrounding the violation rather than use of standard terms and conditions in every situation.

The board responded that probation terms are adapted to each situation. There are a number of probation terms that the board has found valuable in all cases and those are imposed on all probationers. There are also a range of optional probation terms that can be imposed based on the circumstances in the given case.

The commenters further stated that requiring pharmacy technicians on probation to become certified by the Pharmacy Technician Certification Board should be revised or eliminated.

The board responded that the examination requirement is imposed because the technician has demonstrated an inability to comply with the legal or skill requirements of the job. The board has only a simple registration requirement for technicians. Consequently, the examination serves as a metric for establishing that the technician has the specific knowledge and skill to perform the duties required of a technician.

The commenters further stated that the disciplinary guidelines should not indicate that a failure to comply with terms of probation should automatically be a violation of probation.

The board responded that the terms of probation are not optional. Taking the step proposed by the commenters would dramatically undermine the board's ability to enforce probation. Licensees subject to professional discipline are placed on probation to assure the public safety. During the term of probation the licensee is demonstrating his/her ability to comply with the pharmacy law and assure public safety, and failure to comply with the terms of probation under such conditions is a significant event.

The commenters further stated that the board does not itemize its costs for recovery in settlement discussions. Rather, a lump sum is used as "leverage" in the negotiations for a settlement.

The board responded that the board is not required to provide the respondent with a detailed cost accounting for cost recovery. The statute allows the board to recover the reasonable costs of the investigation.

There were several additional issues raised in the written comment including the lack of availability of the text of the proposed Disciplinary Guidelines at the board's web site

The board responded that the text of the proposed Disciplinary Guidelines was mailed to all individuals on the regulatory notice list and copies of the document were available from the board on request. The Disciplinary Guidelines were posted on the website for a period of time during the comment period. Furthermore, at the time this regulatory action was notice, the law did not require the board to provide the text of the proposed Disciplinary Guidelines on its websites. Furthermore, the proposed disciplinary guidelines were released and discussed at two board meetings prior to the filing of the notice of proposed action. The board also conducted an informational hearing to obtain public comment prior to filing the notice of proposed action.

The commenters further stated that the board's composition does not comply with the statutory requirement that at least five members be practicing pharmacists.

The board responded that this comment does not address the Disciplinary Guidelines. If the commenters have concerns regarding the appointment of pharmacists to the board, they should take them up with the Governor who is their sole appointing authority.

Lastly, the commenters stated that the board is not required by statute to produce its guidelines in a particular format; therefore, an approach that includes general statements regarding the factors to be considered and mitigating evidence without standard terms of probation or categories of violation would be preferable.

The board responded that the Disciplinary Guidelines can be established in any form desired by the board. However, the Disciplinary Guidelines are designed to maximize the consistency of board disciplinary actions while preserving the flexibility required to make the discipline appropriate for the case at hand.

Comment Received During the January 24, 2001 Regulation Hearing.

Mr. John Cronin repeated some of the concerns articulated in the written comment he submitted on behalf of the California Pharmacists Association, Longs Drug Stores, United Food and Commercial Workers' Union Local 770 and the Guild of Professional Pharmacists.

The board responded to those comments above.

Mr. Alan Pope, representing Longs Drug Stores, stated that pharmacists in similar situations are treated differently when subjected to board enforcement action. Mr. Pope further commented that better communication is required to make the board's disciplinary processes clear to its licensees.

The board responded that the purpose of the disciplinary guidelines is to provide consistency in the application of professional discipline. The board would welcome specific comment on provisions of

the Disciplinary Guidelines that treat similarly situated respondents inconsistently. The board further responded that the Disciplinary Guidelines are developed and disseminated to provide consumers and the regulated community with information about the board's disciplinary activity.

Mr. Ron Marks repeated some of the concerns articulated in the written comment he submitted.

The board responded to those comments above.

Mr. Marks stated that a pharmacist on probation should be allowed to act as a pharmacist-in-charge (PIC) with the appointment of a consultant pharmacist to monitor his/her activity.

The board responded that the pharmacists on probation should not be permitted to act as a PIC. The PIC is responsible for assuring the pharmacy's compliance with all state and federal laws governing the pharmacy. A pharmacist who has demonstrated an inability to comply with the law governing professional practice or has demonstrated an inability to comply with other standards of professional practice is a poor candidate for a position of such responsibility.

Mr. Marks further stated that the board establish guidelines for settlement proposals.

The board responded that settlements are the product of negotiation between the board and the respondent. Guidelines would have the effect of constraining the freedom of the respondent and the board in those negotiations and actually could result in making it more difficult to arrive at mutually agreeable settlement terms. The board utilizes the disciplinary guidelines to establish the terms of any settlement. Counsel for the respondent can use the guidelines for the same purpose.

Comment Received During the 15-Day Comment Period (February 4, 2001 to February 19, 2001)

The Board of Pharmacy received no comment during the 15 day comment period.

Local Mandate: None.

Business Impact: The Board of Pharmacy has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives: The Board of Pharmacy determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.